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M. Tarver

M. TARVER
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Spiros	Fotinos	Kolonaki, Athens, Greece
Ligia	Panaitescu	Ano Dasos Chaidariou, Attiki, Greece

☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Methods and Devices for Holding a Therapeutic Composition

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ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification *Number of Pages*	14	☐ CD(s), Number	
☒ Drawing(s) *Number of Sheets*	3	☐ Other (specify)	
☒ Application Data Sheet. See 37 CFR 1.76			

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☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Robert M. Asher Date 03/26/03

TYPED or PRINTED NAME Robert M. Asher REGISTRATION NO. *(if appropriate)* 30,445

TELEPHONE 617-443-9292 Docket Number: 1581/135

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S.D Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

Practitioner's Docket No. 1581/135 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Spiros Fotinos, Ligia Panaitescu

Application No.: not yet assigned Group No.: N/A
Filed: herewith Examiner: N/A
For: Methods and Devices for Holding a Therapeutic Composition

Commissioner for Patents
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Robert M. Asher

Signature of person mailing paper or fee

Inventor Information

Inventor One Given Name::	Spiros
Family Name::	Fotinos
Postal Address Line One::	18A I. Statha Str.
City::	Kolonaki, Athens
Country:	Greece
Postal or Zip Code::	106-72
Citizenship Country::	GR

Inventor Two Given Name::	Ligia
Family Name::	Panaitescu
Postal Address Line One::	22, Naxou Str.
City::	Ano Dasos Chaidariou, Attiki
Country:	Greece
Postal or Zip Code::	124-61
Citizenship Country::	GR

Correspondence Information

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PROVISIONAL PATENT APPLICATION

FOR

Methods and Devices for Holding a Therapeutic Composition

Inventors: **Spiros Fotinos**
18A I. Statha Str.
Kolonaki, Athens
Greece
106-72

Ligia Panaitescu
22, Naxou Str.
Ano Dasos Chaidariou, Attiki
Greece
124-61

Attorney Docket: 1581/135

Attorneys: BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
(617) 443-9292

[redacted]

Attorney Docket: 1581/135

Methods and Devices for Holding a Therapeutic Composition

Background of the Invention

The present invention relates to techniques and devices for packaging or holding objects that have a therapeutic composition.

In manufacturing pharmaceuticals and other substances to induce some type of therapeutic effect, an important consideration is how the quantities, or specific doses, of the therapeutic composition are distributed to the consumer. Techniques of manufacturing the therapeutic composition should be integrated with methods and devices for holding and/or packaging the composition; this may allow advantages such as streamlining production labor and decreased manufacturing costs. In the particular instance where the therapeutic composition is embodied with an active agent-containing film, the film may be relatively sensitive, fragile, and easily deformable or damaged. Thus, integrating manufacturing techniques with design considerations for packaging and holding therapeutics may have the added advantages enhancing product stability and quality. Simultaneously, the risk of product deterioration may be decreased by minimizing exposure of the product to the environment (e.g. light, air, heat, moisture, etc.), isolating the product from contact with people, and facilitating product handling (e.g. preventing the stacking of films that may adhere to one another).

Summary of the Invention

In a first embodiment of the invention, a device for holding therapeutic compositions includes a support substrate; a pattern of adhesive applied to a side of the support substrate; and an array of discrete film segments that are removably attached to the support substrate through contact with the adhesive. The support substrate may be made of a transparent material; in addition, the substrate may be a release liner. The pattern of adhesive may be a set of parallel lines. The embodiment may be sterilized or packaged in a separate container or pouch.

A method for producing the first embodiment first involves providing a pattern of adhesive applied to a side of a final support substrate. A film with the therapeutic composition is removably attached to the final support substrate through contact with the pattern of adhesive. Finally, the film is segmented into an array of discrete film segments that remain attached to the final support substrate through contact with the pattern of adhesive. Before the film is removably attached to the final support substrate, the film may also be removably attached to an initial support substrate. In that case, the initial support substrate is delaminated from the film before the film is segmented. The initial film substrate may have a coated surface of Teflon or silicon. Segmenting the film may include removing portions of the film that are not film segments.

In a second embodiment of the invention, another device for holding therapeutic compositions includes a support substrate; an array of discrete film segments carrying the therapeutic composition, that are removably attached to a side of the support substrate; and a sealing material that is heat sealed to the support substrate and covers the array of film segments. The support substrate may be made of a transparent material. The support substrate may also be a polyethylene-coated paper, wherein the side of the support substrate that contacts the film segments is glossy and unexposed to Corona treatment. The sealing material may be made of a material that is transparent, or may be tear resistant. One type of sealing material that may be used with the second embodiment is a polyester sheet double-side coated with polyethylene, the side of the sealing material heat sealed to the support substrate being glossy; the polyester sheet may also be ultra-dimensional stable. The sealing material may also be heat sealed around each film segment to isolate the film segments from one another. Another heat-sealing arrangement that may be used is to avoid heat sealing the corners of the support substrate to allow easier separation of the support substrate from the sealing material by a user. The embodiment may be sterilized.

A method for producing the second embodiment involves applying a film including the therapeutic composition to a portion of a side of a support substrate; segmenting the film into an array of film segments, the film segments being removably attached to the support substrate; superposing a sealing material to cover the film segments; and heat sealing the sealing material to the support substrate. The step of applying a film may include applying a polymer gel or polymer solution to the support substrate and allowing the solution or gel to

dry thus forming the film. The step of segmenting the film may include removing a portion of the film.

In a third embodiment of the invention, an alternate method for holding a therapeutic composition involves depositing each of a plurality of film segments into blister cavities formed in a substrate; superposing a sealing material over the blister cavities and in contact with the substrate; and attaching the sealing material to the substrate. The step of attaching the sealing material may include heat sealing the sealing material to the substrate. Polyvinyl chloride, a combination of polyvinyl chloride and polyvinylidene chloride, or aluminum may be used for the substrate. The substrate material may be transparent. The sealing material may be transparent, or may be tear-resistant. One type of material that may be used for the sealing material is lacquered aluminum foil.

A variation of the third embodiment includes practicing the step of depositing each of a plurality of film segments into blister cavities formed in a substrate by depositing film segments on the substrate and forming blister cavities in locations of the substrate where film segments are deposited. In a second variation, the step of depositing each of a plurality of film segments into blister cavities is performed by laminating a film on the substrate and segmenting the film into segments while substantially simultaneously forming blister cavities in the substrate, at positions where film segments are created. In a third variation, the step of depositing each of a plurality of film segments into blister cavities is performed by forming a plurality of blister cavities in a substrate, laminating a film over the substrate on a side such that the blister cavities protrude away from the film, and impinging a punch against the film on a side opposite the substrate, causing film segments to be created and deposited into the blister cavities.

The method of the third embodiment may also be practiced by omitting the steps of covering the blisters with a film and displacing segments of the film. These steps are replaced by the providing of quantities of the therapeutic composition that are individually placed in the blisters of the substrate.

When film segments are used with the three embodiments, the film segments may be formed such that each contains the same quantity of a therapeutic composition. The amount of therapeutic composition in a film segment may correspond with a particular dose of the therapeutic composition.

All of the methods described may be carried out by a continuous process. In addition, the methods may be modified to create a sterile product.

The invention will more readily be understood by reference to the following description taken with the accompanying drawings that depict various embodiments. The drawings are intended to provide a better understanding of the invention, but are in no way intended to limit the scope of the invention.

Brief Description of the Drawings

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

Fig. 1a is a plan view of a device for holding therapeutic compositions in accordance with an embodiment of the invention.

Fig. 1b is a side view of a device for holding therapeutic compositions in accordance with an embodiment of the invention.

Figs. 2a - 2c is a series of side views illustrating the steps for making a device for holding film segments to a substrate material, covered by a sealing material, embodiment.

Figs. 3a – 3c is a series of schematic side views of the steps for making a device for holding therapeutic compositions in a blister cavity-formed substrate attached to a sealing material embodiment.

Detailed Description of Specific Embodiments

The embodiments described herein refer to methods and devices for holding a plurality of therapeutic compositions. The methods and devices may be employed to hold a plurality of film segments having the therapeutic composition. The film segments may be formed from a film that includes the therapeutic composition and may be configured in any desired shape and size.

For some embodiments described herein, the film segments **115, 215, 315** may be composed from a film of dried polymer solution or dried polymer gel, either of which may also be hydrophilic in nature before drying occurs. The polymer gel or polymer solution may be formulated with a level of viscosity sufficient to allow the gel or solution to hold a

specific configuration while drying occurs.. The drying time depends upon a variety of factors that may include the type of solvents used, their concentration, the nature and concentration of the other constituents, the film thickness, the sensitivity of active components to high temperature, the air mass convected over the gel or solution, and the speed of film formation. For example, with heat sensitive materials, relatively low temperatures are preferred, requiring longer drying periods. Some embodiments may require a drying time of several minutes.

Polymers that may be utilized in the film segments **115, 215, 315**, and the film **110, 210, 310**, include, for example, polyurethane, polyvinyl pyrrolidone (PVP) and hydroxypropyl methylcellulose (HPMC). A variety of materials including cellulose, starch and their derivatives, proteins, gelatins, etc may also be used. Other polymers include polymers of natural origin. One such embodiment is a plant prolamine, an example being gliadin, combined with other additives of natural origin; such additives may include a polar lipid, such as a ceramide. Each film segment **115, 215, 315** contains some amount of the therapeutic composition to be delivered. A solvent, preferably ethanol when PVP or HPMC is used, is added to the polymer to make the solution.

The therapeutic composition utilized in the film may belong to any therapeutic category. Examples of possible therapeutic compositions include pharmaceuticals, cosmetics, food supplements, herbals, and botanicals. The therapeutic composition may be directed toward oral or topical application, such as epidermal, transdermal, or transmucosal. The amount of therapeutic composition may be the same in each film segment **115, 215, 315**, and may also constitute a particular dosage of the therapeutic composition.

Embodiments of the dried polymer film segments have thicknesses of 0.03, 0.05, and 0.06 millimeters, each segment having a surface area varying between 0.8 and 3.0 square centimeters. The film may also contain additional components that alter particular physical and chemical properties. For example, a film may include a plasticizer and an antioxidant.

In a specific example, dried polymer film segments include an active agent for treating erectile dysfunction, a polymer, a plasticizer, and an antioxidant. The dried film segments are circularly shaped with a surface area of 2.0 cm^2 and a thickness of 0.05 mm.

Though the embodiments described herein refer specifically to holding film segments with a therapeutic composition, these embodiments may also be used to hold other carriers

with the therapeutic composition including various types of transdermal, epidermal, or transmucosal delivery systems (e.g. patches), tablets, capsules, and pills.

In some instances, sterilization of the device holding the therapeutic compositions helps preserve the compositions in a particular state before their use. Thus alternatives to the embodiments described herein include application of methods and techniques known in the art to create the therapeutic compositions, carriers such as the film segments **115, 215, 315,** substrates **100, 200, 300,** adhesive **140,** sealing materials **220, 320,** and other materials in a sterile manner.

Referring to Fig. 1, a support substrate **100** is shown holding a plurality of film segments **115** each having an amount of the therapeutic composition. The film segments **115** are removably attached to the support substrate **100** by an adhesive **140,** allowing the film segments **115** to be separated from the support substrate **100** by a user without damaging the segments **115.**

The support substrate **100** may be composed of any type of material that allows the film segments **115** to be removably attached to the support substrate **100** with an appropriate adhesive **140.** Preferred substrate materials include polyester, polystyrene, high density polyethylene, Teflon, paper, super-calendered (smoothed) paper, and polyurethane films. Laminates of the aforementioned materials may also be utilized. The support substrate **100** may be a release liner for the film segments **115.** In addition, the support substrate **100** may be transparent, allowing a person to view the film segments **115** through the support substrate **100.**

The adhesive **140** may be applied in a particular pattern on the support substrate **100.** For example, the adhesive **140** may constitute sets of closely spaced parallel lines **145** that allow the film segments **115** to be arranged in the pattern of a rectangular matrix, as depicted in Fig. 1a. In a particular embodiment, the adhesive is applied in three pairs of adhesive lines, each lines being approximately 80 millimeters long, 2 millimeters wide, and 0.02 millimeters thick. The adhesive **140** allows the film segments **115** to be removably attached to the support substrate **100.** In addition, the adhesive **140** is chosen such that it does not adversely affect the chemical or physical nature of the therapeutic composition or film segments **115.** Examples of possible adhesives for use with the embodiment include, but are

not limited to, Duro-Tak® (produced by National Starch), Gelva® (produced by Solutia), and other commercially available polyacrylic adhesives.

One method for making the device depicted in Fig. 1a includes the steps of: (a) providing a final support substrate **100** with a pattern **145** of adhesive **140** in contact with a side of the support substrate **100**; (b) removably attaching a film **110** with the therapeutic composition to the final support substrate **100** through contact with the pattern of adhesive **145** as shown in Fig. 1b; and (c) segmenting the film **110** to form an array of film segments **115** attached to the final support substrate **100** through contact with the adhesive **140**. In a particular embodiment of the method, the step of removably attaching the film **110** to the final support substrate **100** includes providing the film **110** with the therapeutic composition removably attached to an initial support substrate; bringing the film **110** in contact with the pattern of adhesive **140**; and delaminating the initial support substrate from the film **110**, leaving the film **110** attached to the final support substrate **100**.

In the particular method described above, the initial support substrate may be composed of any material that has the property of adhering to the film **110** more weakly than the final support substrate **100** adheres to the film **110**. The film's adherence to the initial support substrate may be an intrinsic property of the two surfaces, or may be facilitated by the use of an adhesive. Possible initial support substrates include release liners. Release liners for the initial support substrate may include a side, which contacts the film **110**, being coated with either silicon or Teflon.

Segmenting the film **110** into an array of film segments **115** may include one or more processes, non-exhaustive examples being cutting and removing of the film **110**. In a particular segmenting process, kiss-cutting of the film **110** is performed. Kiss-cutting involves making cuts that penetrate the film **110**, while not penetrating the support substrate **100**. The kiss-cutting is followed by removal of a portion of the film from the support substrate **100**, leaving discrete film segments **115** that adhere to the support substrate **100** by contact with adhesive **140**, as depicted in Fig. 1a. The remaining film that is not utilized as film segments **115** may be discarded or recycled to formulate more film.

The steps of the method may be performed to produce a continuous product. In such an instance, an additional step of cutting the final support substrate **100** with attached film segments **115** into discrete sets is included. Machinery, such as the Allied Gear and Machine

Co.'s Flexomaster IB press, may be utilized to perform one or more steps of the method continuously. In an embodiment of the method, the step of segmenting the film may be performed by the Flexomaster IB press. In this embodiment, the film **110**, support substrate **100**, and adhesive **140** are provided as a continuous laminate that is rolled up. The laminate is unrolled by the machine and kiss-cut by a first cutting tool, and perforated and scored by a second cutting tool. The machine may also be configured to perform some preprocessing steps on the laminate before kiss cutting occurs. The cutting tools are configured to accommodate the specific film thickness and support substrate utilized. Film **110** that is not utilized in the therapeutic composition, scrap, is delaminated from the original laminate and wound up in a roll. The remaining laminate, including film segments **115** attached to a support substrate **100** through contact with adhesive **140**, is rewound on a roll for further processing.

One or more sets of the film segments **115** attached to the final support substrate **100** may be packaged in a pouch, or other container, to protect the assembly from potential hazards that may include physical damage, contamination, light exposure, or other environmental elements.

Another embodiment of a device for holding a therapeutic composition is shown in Fig. 2c. In this embodiment, film segments **215** are removably attached to a support substrate **200** without the use of an adhesive; adhesion of the film segments **215** to the support substrate **200** is due to the nature of the interaction between the segments **215** and the support substrate **200**. Minor self-adhesive properties of the film segments, substrate surface roughness (surface irregularities created by a particular treatment method), and temporarily induced electrostatic charges provide some examples of mechanisms that result in adhesion between the segments **215** and support substrate **200**. A sealing material **220** covers the film segments **215** so that the segments are protected in a sandwich between the support substrate **200** and the sealing material **220**. The sealing material **220** is heat sealed to the support substrate **200**, to enclose the film segments in a sealed package. The film segments **215** are protected from potential hazards that may include physical damage, contamination, light exposure, and other environmental conditions.

The support substrate **200** may be composed of any type of material that allows the film segments **215** to be removably attached to the support substrate **200** and does not cause

adverse physical or chemical changes to the nature of the therapeutic composition or film segments **215**. Examples of acceptable support substrate materials include paper or plastic sheets. The support substrate **200** may be a release liner. In a particular embodiment, the support substrate **200** is composed of a polyethylene-coated paper. The side of the polyethylene-coated paper that adheres to the film segments **215** is glossy, and not Corona treated, i.e. the side has a smooth, reflective surface that has not been treated to introduce any surface irregularities. This insures that adhesion of the film segments **215** to the support substrate **200** is not so strong as to prevent the segments **215** from being removed without damage. The support substrate **200** may be also be made of a transparent material, allowing persons to view the film segments through the support substrate **200**.

One embodiment of a sealing material **220** utilizes a polyester sheet double side coated with polyethylene, the surface of the film that contacts the support substrate **200** being glossy. In particular, this embodiment of the sealing material **220** may be configured to be especially stable. Examples of the embodiment include the ultra-dimensional stable polyester films produced by Loparex. The films are polyester films coated with a layer of low-density polyethylene on each side. The films do not lose moisture when heated, and, therefore, do not change their dimensions upon heating. The films are very stable liners that do not tend to curl.

The sealing material **220** may be composed of any material that may be heat sealed to the support substrate **200**. The sealing material **220** may be transparent, allowing the film segments **215** to be seen through the sealing material **220**. The sealing material **220** may also be chosen to be tear resistant.

The sealing material **220** may be heat sealed to the support substrate **200** such that each film segment **215** is isolated from the other film segments **215**. The sealing material may also be intentionally unattached to the support substrate in particular locations, e.g. the corners of the sealing material, to allow ease of separation of the sealing material from the support substrate by a user.

As shown in Figs. 2a – 2c, a method for making the device includes the steps of applying a film **210** having the therapeutic composition to a side of a support substrate **200**; segmenting the film **210** into film segments **215**; covering the film segments **215** with a sealing material **220**; and heat sealing the sealing material **220** to the support substrate **200**.

The film segments **215** are attached to the support substrate **200**, but may be removed therefrom without damage to the film segments **215**. In particular, the method may include using a polymer gel or polymer solution to make the film **210**, and include the step of drying the film **210** after the film **210** is applied to a support substrate **200**.

The step of segmenting the film **210** may include kiss-cutting the film **210** and removing the film portions that are not utilized as film segments **215** on the support substrate **200**. Excess film may either be discarded or recycled to formulate more film. A continuous process may be employed to carry out the steps of this method; in such a case, the method further includes a step of cutting the attached support substrate **200** and sealing material **220** holding a plurality of film segments **215** to create sets of the held film segments **215**.

In a preferred embodiment of the method, a coating machine applies the polymer solution or polymer gel to the support substrate, forming a laminate sheet. The solution or gel is dried, and the laminate wound up into a roll. The Allied Gear and Machine Co.'s Flexomaster IB press, that was described earlier to create the embodiment in Fig. 1, can be utilized with the roll created by the coating machine to kiss-cut and delaminate the scrap material not being packaged.

Referring to Figs. 3a – 3c, an alternate method of producing a device for holding film segments with a therapeutic composition is described. Discrete film segments **315** including the therapeutic composition are deposited into individual blisters cavities **305** of a substrate material **300**. The film segments **315** may be formed from an original film **310** containing the therapeutic composition. A sealing material **320** is placed over the blisters cavities **305** containing the film segments **315** and attached to the substrate material **300** to contain the film segments **315**. The film segments **315** may be free from attachment while contained within the blister cavity **305** covered by the sealing material **320**.

The substrate material **300** may be any material to which blisters cavities **305** may be formed. Blister cavities **305** are stable impressions in the substrate material **300** that are sized to contain individual film segments **315**, as depicted in Figs. 3b and 3c. When the substrate **300** is oriented such that the blisters **305** are in a concave downward orientation, as depicted in Figs. 3a – 3c, individual film segments **315** may be contained within each blister cavity **305**, with an open top surface as depicted in Fig. 3b. Examples of suitable materials

for the substrate material **300** include, but are not limited to, polyvinyl chloride, a combination of polyvinyl chloride and polyvinylidene chloride, and aluminum.

The formation of blister cavities **305** in the substrate material **300** and depositing of film segments **315** into the blister cavities **305** may be performed using various techniques. In one technique, film segments **315** are provided on a blister cavity-free substrate material. The film segments **315** may be formed and provided on the substrate material **300** utilizing the methods described earlier to form the embodiments depicted by Fig. 2. The film segments **315** may be held in place on the substrate material **300** by electrostatic charges. Next, a machine forms blister cavities **305** in the substrate material **300** at positions where film segments **315** are located. The blister cavities **305** may be formed by any technique known to those in the art. In one embodiment, the blister cavities **305** are formed by moving the substrate **300** over an appropriately sized and shaped orifice in a surface of a machine. The substrate material **300** is drawn into the orifice, deforming permanently into a shape confined by the orifice and creating the blister cavity **305**. The process of deforming the substrate material **300** may utilize heat or mechanical force. Since each blister cavity **305** is formed adjacent to a film segment **315**, upon cavity formation the segment **315** is simultaneously deposited into the cavity **305**.

In another technique, a film **310** is placed over a blister cavity-free substrate material. A machine forms blister cavities **305** in the substrate material while also displacing a film segment **315** from the film **310** into each blister cavity **305**. In one embodiment, the blister cavities **305** are formed by drawing the substrate material **300** into an orifice, as discussed above. At approximately the same time, film segments **305** are displaced from the film **310** by impinging a punch **330** against the film **310** on a side opposite the substrate material **300**. The shape of the punch may be chosen to create a desired film segment size. The punch **330** may have a surface that impinges upon the film **310** that is flat or curved. The punch contact surface may also have the shape of an annular ring or frame of any desired shape or size. The punch **330** preferably has edges that are sharp enough to cut the film **310**. The punch **330** forms film segments **315** that are deposited into the blister cavities **305**. The punch **330** is subsequently withdrawn.

In a third technique, a substrate material **300** with preformed blister cavities **305** is provided. The blister cavities **305** may be formed by any technique known in the art

including the particular technique described above. A film **310** with the therapeutic composition is positioned over the substrate material **300** on a side of the substrate material **300** in which the blister cavities **305** protrude away from the film **310**, as depicted in Fig. 3a. A machine impinges the film **310** with a punch **330** on a side opposite the substrate material **300** in positions over the blister cavities **305**. The punch contact creates a film segment **315** which is separated from the film **310** and deposited into the blister cavity **305**.

Subsequent to the depositing of film segments into the blister cavities, a sealing material is used to contain the film segments within the cavities. The sealing material **320** may be any material that may be attached to the substrate material **300**. In a particular embodiment, the sealing material **320** is heat sealable to the substrate material **300**. One example of a sealing material **320** is lacquered aluminum foil. Other properties of the sealing material **320** that may be desirable include transparency and tear resistance.

The sealing material **320** is placed over openings of the blisters **305** that contain the film segments **315**. Portions of the sealing material **320** are in contact with the substrate material **300**. In a particular configuration, the sealing material **320** contacts the portions of the substrate **300** that do not constitute a blister cavity **305**. Locations of contact between the sealing material **320** and substrate material **300** may be heat sealed, thus containing the film segments **315** within the blister cavities **305**. The heat sealing may take place around each blister cavity to ensure isolation of each film segment. The corners of the substrate or sealing material may not be heat sealed to allow easier separation of the layers when access to the film segments is desired by a consumer.

The method may be practiced in a continuous process that forms a continuous substrate with blister cavities **305**, film segments **315**, and sealing material **320**. A plurality of blister cavities **305** and/or film segments **315** may be formed in a batch process that is carried out successively. The continuous method would include the step of cutting the substrate **300** to provide discrete sets of the film segments **315**.

In an alternative to this blister packaging method, the film segments are preformed and deposited into preformed blister cavities in a substrate material. In this embodiment, the method and device are not necessarily limited to the packaging of film segments but may include packaging of therapeutic compositions in other forms including patches, tablets, and pills.

The aforementioned embodiments are intended to be merely exemplary; numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention.

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Methods and Devices for Holding a Therapeutic Composition

Abstract

Methods and devices for holding a therapeutic composition are described. A first embodiment involves a support substrate that supports a discrete array of film segments having the therapeutic composition, the film segments being attached to the support substrate by a pattern of adhesive. A second embodiment involves a support substrate that supports a discrete array of film segments having the therapeutic composition without the use of an adhesive; the embodiment includes the use of a sealing material that is heat sealed to the support substrate to contain the film segments. A third embodiment involves a substrate holding the film segments in blisters; a sealing material is attached to the substrate to contain the segments in the blisters.

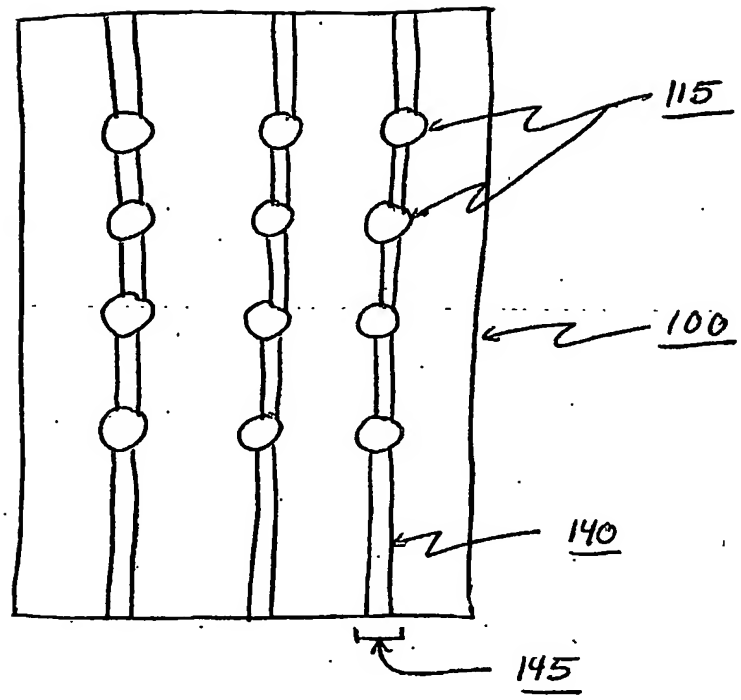

FIGURE 1a

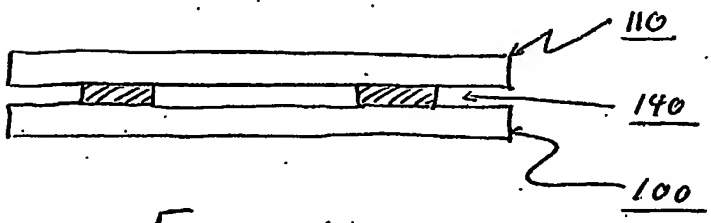

FIGURE 1b

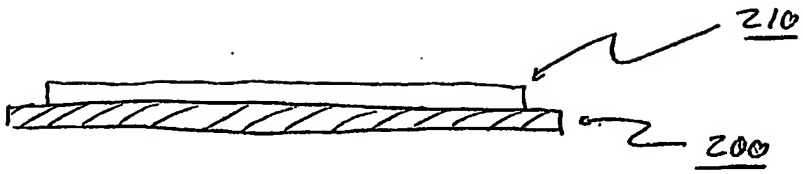

FIGURE 2a

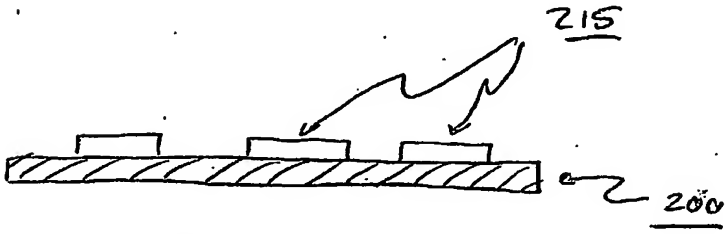

FIGURE 2b

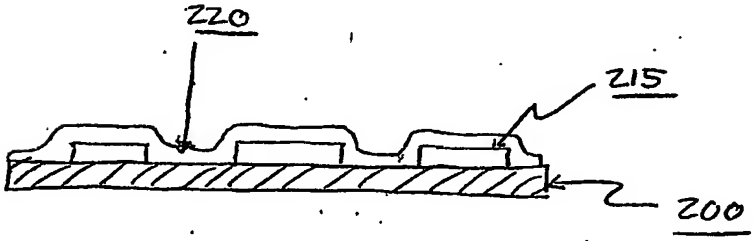

FIGURE 2c

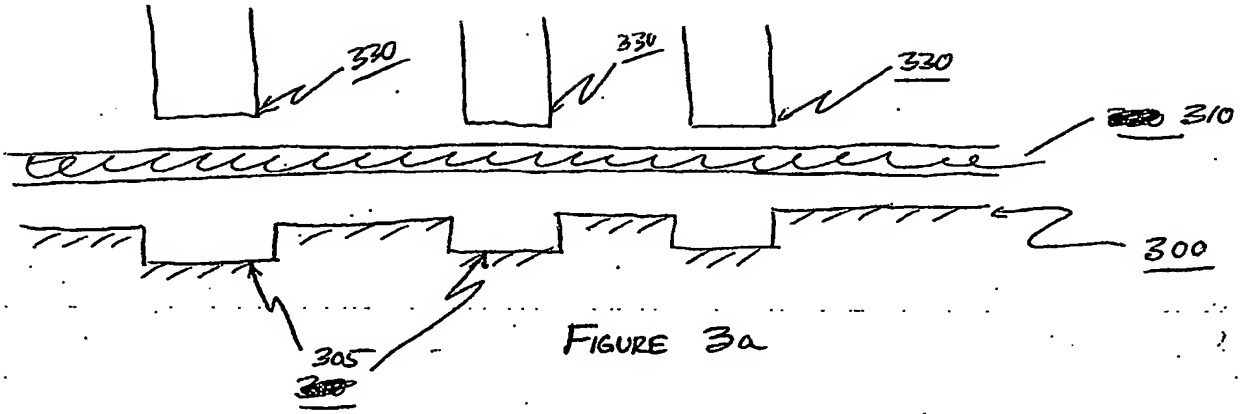

FIGURE 3a

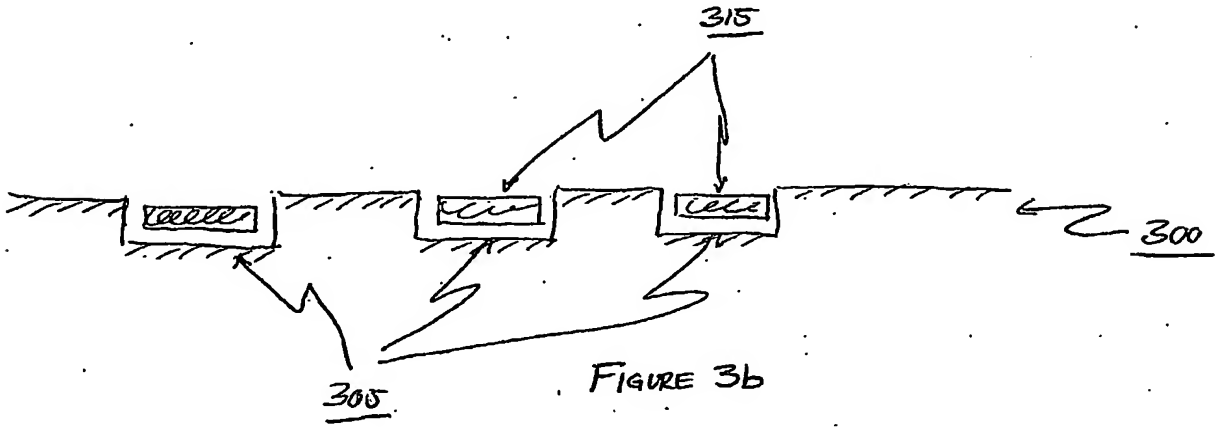

FIGURE 3b

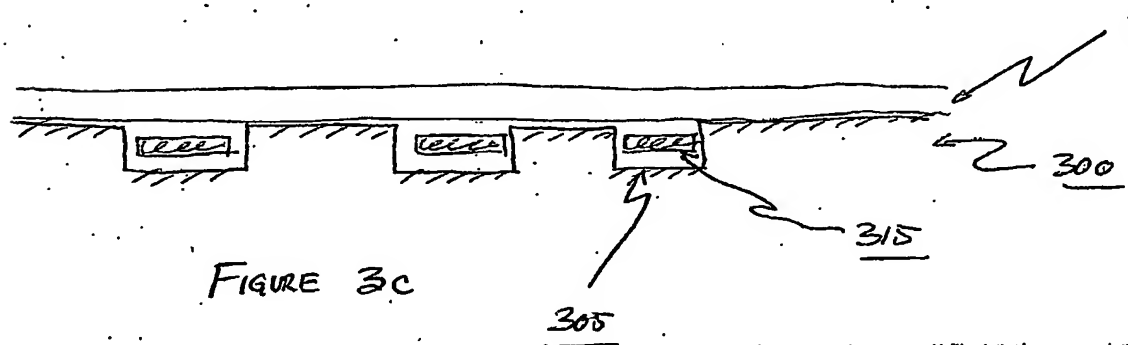

FIGURE 3c